

§ 801.417

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system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.

(c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25 °C (77 °F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

[43 FR 11318, Mar. 17, 1978]

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) *Hearing aid* means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) *Ear specialist* means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) *Dispenser* means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) *Audiologist* means any person qualified by training and experience to

specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) *Sale or purchase* includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) *Used hearing aid* means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(a) Use of the hearing aid.

(b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(c) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c)(2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.

(xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to as-

sess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-1996 (ASA 70-1996) (Revision of ANSI S3.22-1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard Dr., rm. 240, Rockville, MD 20850, and or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/>

federal_register/code_of_federal_regulations/ibr_locations.html. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other

labeling for each type of hearing aid on or before August 15, 1977.

[42 FR 9294, Feb. 15, 1977, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 30154, July 24, 1985; 54 FR 52396, Dec. 21, 1989; 64 FR 59620, Nov. 3, 1999; 69 FR 18803, Apr. 9, 2004]

§ 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements—*
(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

- (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by _____ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

- (1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been,